10/694,874

REMARKS

Applicants note that upon entry of this amendment claims 17-38 are pending and under consideration as claims 1-5, 10 and 16 are under request to be canceled. Claims 6-9 and 11-15 have been withdrawn from consideration.

Specification Objection

The Examiner has objected to the website addresses found on page 2, line 2 and page 10, line 22 of the specification. Applicants have deleted these website addresses so that the specification now complies with M.P.E.P. 608.01. Accordingly, Applicants respectfully request that the objection to the specification be withdrawn.

Claim Rejections 35 U.S.C. § 112, first paragraph

The Examiner has rejected claims 1-5, 10 and 16 under 35 U.S.C. §112, first paragraph, as allegedly lacking enablement. The Examiner asserts that one of skill in the art to which the invention pertains would not be able to practice the claimed invention without undue experimentation because Applicants' specification does not enable the claims as they were previously written. Applicants respectfully disagree with the Examiner's rejection, but have nevertheless voluntarily drafted new claims in order to more clearly point out the characteristics and features of the claimed subject matter.

Claim Amendments

New claim 17 as well as dependant claims 18-20 and 33-35 is drawn to an isolated antibody (either polyclonal or monoclonal as well as a hybridoma cell line producing the monoclonal) that binds human IRS-1 when phosphorylated at serine 1101, but does not bind human IRS-1 when not phosphorylated at serine 1101. Due to the high homology of the sequences it is further expected that the antibody will also bind human to IRS-2 when phosphorylated at serine 1149, murine IRS-1 when phosphorylated at serine 1095 and murine IRS-2 when phosphorylated at serine 1138, but not bind any of the three aforementioned proteins when not phosphorylated at their respective serine sites. Support for these new claims is found in throughout the specification and particularly on page 34 lines 4-8, page 34, 28-30 to page 35 line 2.

APPLICANTS: U.S.S.N.:

Polakiewicz et al.

10/694,874

New claim 21 as well as dependant claims 22-24 and 33-35 is drawn to an isolated antibody (either polyclonal or monoclonal as well as a hybridoma cell line producing the monoclonal) that binds human IRS-2 when phosphorylated at serine 1149, but does not bind human IRS-2 when not phosphorylated at serine 1149. Due to high homology between the sequences it is further expected that the antibody of claim 21 will also bind to human IRS-1 when phosphorylated at serine 1101, murine IRS-1 when phosphorylated at serine 1095 and murine IRS-2 when phosphorylated at serine 1138, but not bind any of the three aforementioned proteins when not phosphorylated at their respective serine sites. The specification supports and enables new claim 21 as well as dependant claims 22-24 and 33-35 throughout the specification. A person of skill in the art would need only construct an amino-acid phospho-peptide antigen with the sequence grrhs*setfsstt (where *s = phosphoserine; See bold-face sequence in Figure 2) and follow the procedure laid out in Examples 1 & 3 of the present specification in order to arrive at the antibody of claim 21 and dependant claims 22-24 and 33-35.

New claim 25 as well as dependant claims 26-28 and 33-35 is drawn to an isolated antibody (either polyclonal or monoclonal as well as a hybridoma cell line producing the monoclonal) that binds murine IRS-1 when phosphorylated at serine 1095, but does not bind murine IRS-1 when not phosphorylated at serine 1095. Due to high homology between the sequences it is further expected that the antibody of claim 25 will also bind to human IRS-1 when phosphorylated at serine 1101, human IRS-2 when phosphorylated at serine 1149 and murine IRS-2 when phosphorylated at serine 1138, but not bind any of the three aforementioned proteins when not phosphorylated at their respective serine sites. The specification supports and enables new claim 25 as well as dependant claims 26-28 and 33-35 throughout the specification. A person of skill in the art would need only construct an amino-acid phospho-peptide antigen with the sequence crrhs*setfsa (where *s = phosphoserine; See bold-face sequence in Figure 13) and follow the procedure laid out in Examples 1 & 3 of the present specification in order to arrive at the antibody of claim 25 and dependant claims 26-28 and 33-35.

New claim 29 as well as dependant claims 30-32 and 33-35 is drawn to an isolated antibody (either polyclonal or monoclonal as well as a hybridoma cell line producing the monoclonal) that binds murine IRS-2 when phosphorylated at serine 1138, but does not bind murine IRS-2 when not phosphorylated at serine 1138. Due to high homology between the sequences it is further expected that the antibody of claim 29 will also bind

APPLICANTS:

Polakiewicz et al.

U.S.S.N.:

10/694,874

human to IRS-1 when phosphorylated at serine 1101, human IRS-2 when phosphorylated

at serine 1149 and murine IRS-1 when phosphorylated at serine 1095, but not bind any of

the three aforementioned proteins when not phosphorylated at their respective serine sites.

The specification supports and enables new claim 29 as well as dependant claims 30-32

and 33-35 throughout the specification. A person of skill in the art would need only

construct an amino-acid phospho-peptide antigen with the sequence grrghs*setfsst (where

*s = phosphoserine; See bold-face sequence in Figure 14) and follow the procedure laid

out in Examples 1 & 3 of the present specification in order to arrive at the antibody of

claim 29 and dependant claims 30-32 and 33-35.

New claims 36-38 are drawn to kits for the detection of phosphorylated human

IRS-1 (Ser1101), phosphorylated human IRS-2 (Ser 1149) and PKC theta activity in a

biological sample (respectively). Support for new claims 36-38 can be found through the

specification and specifically on page 30, line 18 to page 31, line 12.

Applicants assert that the present claim amendments do not add new matter and

that the newly drafted claims are fully enabled by the specification. Accordingly,

Applicants respectfully request that the enablement rejection of the December 22, 2006

Office Action be withdrawn.

Conclusion

The present claims are patentable over the prior art and believed to be in condition for

immediate allowance. Reconsideration and withdrawal of the outstanding objections and

rejections is respectfully requested, and early and favorable allowance of these claims is

earnestly solicited. If there are any questions regarding these amendments and remarks, the

Examiner is requested to call the undersigned attorney at the telephone number provided.

Respectfully submitted,

Andrew J. Warner, Esq., Reg. No. 56,049

Associate Intellectual Property Counsel

CELL SIGNALING TECHNOLOGY, INC.

(978) 867-2343

Date: May 22, 2007

10